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EXAMINER

SILVERMAN, ERIC E

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/815,421
Filing Date: March 31, 2004
Appellant(s): HOSSAINY, SYED F.A.

Zhaoyang Li
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/30/2008 appealing from the Office action mailed 3/18/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,110,483	Whitbourne et al.	8-29-2000
WO2004/101018	Paceti et al.	5-8-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 31 – 41, 47 – 49, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,110,483 to Whitbourne et al. in view of WO 2004/101018, of record.

I. Claim interpretation

It is recognized that Applicants may be their own lexicographer. In the instant application, Applicants have used an unusual definition for block copolymers. In the discussion of the nature of the copolymer blocks (pages 4 – 5 of the specification), Applicants explicitly state “[t]he[se] blocks *need not be linked at the ends*, . . .” (emphasis added).

Using Applicants’ definition, a physical mixture of the homopolymers corresponding to the various blocks of a block copolymer is a block copolymer where the blocks are not linked at the ends.

While it is recognized that this is not the typical definition of a block copolymer in the art, Applicants’ right to be his or her own lexicographer is not abridged so long as the atypical definition is clear so as to put readers on notice. In this case, the definition is clear, and readers are put on notice, as to the atypical use of the term “block copolymer”.

II. Reason for the rejection

The claims require a medical device, specifically a stent, with a two-part coating. The coating must contain a structural component, for which Applicants elected PBMA

(poly (butyl methacrylate)), and a biobeneficial component, for which Applicants elected PEG-PBMA-PEG. Dependent claims specify the ratio of the two components.

Whitbourne teaches stents coated with PBMA (claim 7).

Whitbourne does not teach the use of PEG-PBMA-PEG.

The WO reference teaches the use of PBMA and PEG as a topcoat for a polymer coated stent (examples 4 and 5). The PEG and PBMA form an interpenetrating polymer mixture, which suffices to read on the elected PEG-PBMA-PEG block copolymer according to Applicants' definition of block copolymer in the instant specification. The topcoat has the advantage of providing a controllable release of a drug in the stent (see Fig. 4, description thereof, and examples).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the topcoat composition of WO on the PBMA coated stent of Witbourne. The motivation is to control the drug release rate. With regard to the ratio of components, this is a matter of mere optimization, wherein the artisan would find the best ratio depending on the desired use. Since WO teaches how to make and provide the topcoat to a stent, the artisan would enjoy a reasonable expectation of success.

(10) Response to Argument

Applicants' sole argument is that the mixture physical mixture of PEG and PBMA disclosed in the art does not read on the term "block copolymer" as Applicants' have defined that term in the instant specification. It is noted that Applicants have defined that term so that the "blocks need not be linked at the ends." Paragraph [0018] of the published specification.

A block copolymer of hypothetical monomers A and B, where the blocks are linked at the ends, can be represented by the following structure:

AAAAAAAAA-BBBBBBBBBBB

When the blocks are "not linked at the ends" as per Applicant's definition, the linkage between the A section and B section is broken. The result is two homopolymers, one with monomer A only, and the other with monomer B only, as follows:

AAAAAAAAA BBBBBBBBBBBB

Thus, a physical mixture of the homopolymers is clearly within the scope of a block copolymer where the blocks are "not linked at the ends" as per Applicants' definition.

Applicant continues by arguing that the term "blocks need not be linked at the ends" is meant to encompass a variety of different structures, as outlined in Scheme II of the Appeal Brief. In analyzing these structures, it is important to note that according to paragraph [0014] of the instant Application, a "block copolymer" must have a linear arrangement of blocks. Of the three structures in Scheme II, the only one that has a linear arrangement of blocks is the topmost structure where the blocks are linked at the end. The other two structures do not have a linear arrangement, and so are not "block copolymers" according to Applicants' definition of that term.

Applicant's unequivocal statement that the blocks of a block copolymer "need not be linked at the ends" can only be understood to expand the meaning of block copolymers beyond structures such as AAAAAAAAAA-BBBBBBBBBBBB. The term

cannot include the structures proposed by Applicant in Scheme II, as those structures do not have "a linear arrangement of polymer blocks", and thus are not block copolymers as that term is used in this Application. The most reasonable understanding of this statement is the inclusion of physical mixtures of the constituent homopolymers, which would be the direct result of eliminating the linkage of the blocks.

Alternatively, even if the non-linear structures in claim 3 are "block copolymers" within the scope of Applicants' definition, this does not exclude a mixture of homopolymers from being block copolymers where the blocks are not attached at the end. Indeed, a physical mixture of homopolymers would be the direct result of unlinking the ends of the constituent blocks in a block copolymer.

In either case, the mixture of the constituent homopolymers, disclosed in the art, clearly reads on block copolymers where the blocks are not linked at the ends, and thus is within the scope of Applicants' definition of that term.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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